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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,330

Applicant(s)

CHEN ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed May 30, 2002, Paper No. 5, is attached to the instant Office action.

Claim Objections

Claim 8 is objected to because of the following informalities: the word "than" in line 2 is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-15, 18-22 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are broadly drawn to a transgenic graminaceous cell and plant comprising a transgene encoding any enzyme of the glycine betaine biosynthetic pathway, including betaine aldehyde dehydrogenase from any source.

The claims do not recite the specific identity of any particular enzyme of the glycine betaine biosynthetic pathway which the transgene encodes. Absent reference to the particular identity of the enzyme encoded by the transgene a critical element of the claimed invention remains undefined, such that the invention is not adequately described. In contrast, the specification only provides guidance for obtaining salt and drought tolerant turfgrass plants comprising a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis*. While the specification indicates that other transgenes encoding betaine aldehyde dehydrogenase from other sources or encoding other glycine betaine biosynthetic enzymes may be used to make the claimed transgenic cells and plants, no guidance is presented with respect to the characterization of these transgenes.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the

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species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 4 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a transgenic graminaceous cell and plant comprising a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* in which the plasmid pRTT120 comprises the transgene.

Since the plasmid pRTT120 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmid pRTT120 is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same plasmid in each occurrence and it is not apparent if such a plasmid is

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readily available to the public. If the deposit of the plasmid is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the plasmid will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

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(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

Claims 1-22 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salt and drought tolerant transgenic turfgrass cells and plants comprising the exemplified transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis*, does not reasonably provide enablement for other salt and drought tolerant transgenic plants comprising other transgenes, or for salt and drought tolerant transgenic turfgrass cells and plants comprising the exemplified transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* wherein the cells are able to grow significantly faster on 0.8% NaCl at P=0.05, or wherein the plants are able to grow significantly faster on 1.2 % NaCl at P=0.05. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a transgenic graminaceous cell and plant, including turfgrass, comprising a transgene encoding an enzyme of the glycine betaine biosynthetic pathway, including betaine aldehyde dehydrogenase from *Atriplex hortensis*, wherein the cell is salt tolerant, including able to grow significantly faster on 0.8% NaCl at P=0.05, wherein the plant is salt tolerant, including able to grow significantly faster on 1.2 % NaCl at P=0.05, and wherein the plant is also drought tolerant.

The specification discloses that transgenic Creeping Bentgrass callus and plants comprising a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* exhibit increased tolerance to 0.8% NaCl and 1.2% NaCl respectively, as compared to nontransformed control plants (Example 1, pages 19-21), but the specification does not disclose whether the cells are able to grow significantly faster on 0.8% NaCl at $P=0.05$, or whether the plants are able to grow significantly faster on 1.2 % NaCl at $P=0.05$. The specification also discloses that transgenic Perennial Ryegrass plants comprising a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* exhibit increased tolerance to drought stress (Example 2, page 25). The specification does not disclose other transgenic plants transformed with other transgenes obtained from other sources. The specification does not provide sufficient guidance for one skilled in the art to determine which non-exemplified transgenes to use and how to express them, because the specification discloses only one transgene encoding only one glycine betaine biosynthetic enzyme that confers drought and stress tolerance when expressed in a transgenic plant.

The ability of a transgene encoding a glycine betaine biosynthetic enzyme in general or a betaine aldehyde dehydrogenase in particular to confer salt or drought tolerance on a transgenic plant is unpredictable. The ability of a glycine betaine biosynthetic enzyme to function to confer salt or drought tolerance would be limited by the cellular environment in which the enzyme is expressed. Enzymatic function would be affected by the amount of enzyme expressed, the availability of substrate, and the presence or absence of other factors that might affect enzyme activity or the accumulation of substrates or products. For example, Rathinasabapathi et al. teach that while rice contains the glycine betaine precursor choline, rice lacks the two subsequent

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glycine betaine biosynthetic enzymes, choline monooxygenase and betaine aldehyde dehydrogenase, needed to convert choline to glycine betaine (Crop Science, May-June 1993, Vol. 33, pages 534-538, Applicant's IDS, see abstract page 534). Consequently, in lacking choline monooxygenase, rice plants might not accumulate sufficient betaine aldehyde substrate for betaine aldehyde dehydrogenase encoded by a transgene to convert to glycine betaine at levels sufficient to confer salt or drought tolerance. Such concerns would also extend to other enzymes in the glycine betaine biosynthetic pathway. Also, Weretilnyk et al. teach that microbial and plant betaine aldehyde dehydrogenases differ in their subunit organization, and may have evolved independently (Archives of Biochemistry and Biophysics, Vol. 271, No. 1, May 15, pages 56-63, Applicant's IDS, see page 62 column 1 second full paragraph). Consequently, microbial and plant betaine aldehyde dehydrogenases may require different conditions in order to exhibit the desired enzymatic function. Such concerns would also extend to other enzymes in the glycine betaine biosynthetic pathway. Other unknown and undisclosed biochemical characteristics of glycine betaine biosynthetic enzymes and betaine aldehyde dehydrogenases from nonexemplified sources could also limit the ability of their transgenes to confer drought or salt tolerance to a transgenic plant.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which nonexemplified glycine betaine biosynthetic enzyme transgenes and betaine aldehyde dehydrogenase transgenes to use and how to express the enzymes they encode such that salt or drought tolerance would be conferred on a transgenic plant, or to obtain faster cell or plant growth using any transgene.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 11-22 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 11 and 14, and claims 8, 12-13, 15-22 and 25 dependent thereon, are indefinite in the recitation of "salt tolerant", as "salt tolerant" is a relative term lacking a comparative basis.

Claims 13 and 21, and claim 24 dependent thereon, are indefinite in the recitation of "drought tolerant", as "drought tolerant" is a relative term lacking a comparative basis.

Claims 19 and 25 are indefinite because they are substantial duplicates. Amendment of claim 25 to depend upon claim 24 would obviate this rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10 and 22 are drawn to seeds, but are not limited to seeds that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that

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plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seeds comprise in their genome the transgene that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-17 and 20-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Guo et al. (Science in China, Series C, October 1997, Vol. 40, No. 5, pages 496-501, Applicant's IDS).

The claims are drawn to a transgenic graminaceous cell and plant comprising a transgene encoding an enzyme of the glycine betaine biosynthetic pathway, including betaine aldehyde dehydrogenase from *Atriplex hortensis*, including the *A. hortensis* gene contained in pRTT120, wherein the cell is salt tolerant, including able to grow significantly faster on 0.8% NaCl at

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P=0.05, wherein the plant is salt tolerant, including able to grow significantly faster on 1.2 % NaCl at P=0.05, and wherein the plant is also drought tolerant.

Guo et al. teach transgenic graminaceous rice cells and plants comprising a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* (page 496 *Abstract*; page 498 Figure 2; page 499 Figures 3 and 4), wherein said *A. hortensis* gene is indistinguishable from the one in pRTT120. The transgenic plants taught by Guo et al. were shown to be salt tolerant (page 496 *Abstract*; page 499 Figure 3). While Guo et al. do not explicitly teach that their transgenic cells are able to grow significantly faster on 0.8% NaCl at P=0.05, or that their transgenic plants are able to grow significantly faster on 1.2 % NaCl at P=0.05, or that their plants are also drought tolerant, such features would be inherent to the transgenic plants and cells taught by Guo et al., as the claims require only the presence of the transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* in the transgenic plants and cells.

Claims 1, 7-14 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (US Patent No. 6,281,411, Issued August 28, 2001, filed January 19, 1996).

The claims are drawn to a transgenic graminaceous cell and plant comprising a transgene encoding an enzyme of the glycine betaine biosynthetic pathway, wherein the cell is salt tolerant, including able to grow significantly faster on 0.8% NaCl at P=0.05, wherein the plant is salt tolerant, including able to grow significantly faster on 1.2 % NaCl at P=0.05, and wherein the plant is also drought tolerant.

Adams et al. teach drought tolerant transgenic graminaceous *Zea mays* cells and plants comprising a transgene encoding an enzyme which catalyzes the synthesis of glycine betaine

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(column 62 claims 1-5; column 64 claims 14-15 and 24). While Adams et al. do not explicitly teach that their transgenic cells are salt tolerant, or that their transgenic cells are able to grow significantly faster on 0.8% NaCl at $P=0.05$, or that their transgenic plants are able to grow significantly faster on 1.2 % NaCl at $P=0.05$, such features would be inherent to the transgenic plants and cells taught by Adams et al., as the claims require only the presence of the transgene encoding an enzyme of the glycine betaine biosynthetic pathway in the transgenic plants and cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathinasabapathi et al. (Planta, 1994, Vol. 193, pages 155-162) in view of Hartman et al. (Bio/Technology, September 1994, Vol. 12, pages 919-923, Applicant's IDS), Xiao et al. (GenBank Accession No. X69770, July 1996), and Marcum (J. Amer. Soc. Hort. Sci., 1994, Vol. 119, No. 4, pages 779-784, Applicant's IDS).

The claims are drawn to a transgenic graminaceous cell and plant, including turfgrass, comprising a transgene encoding an enzyme of the glycine betaine biosynthetic pathway, including betaine aldehyde dehydrogenase from *Atriplex hortensis*, wherein the cell is salt tolerant, including able to grow significantly faster on 0.8% NaCl at $P=0.05$, wherein the plant is

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salt tolerant, including able to grow significantly faster on 1.2 % NaCl at $P=0.05$, and wherein the plant is also drought tolerant.

Rathinasabapathi et al. teach transgenic tobacco cells and plants comprising a transgene encoding betaine aldehyde dehydrogenase from spinach and beet (page 157 Figures 2 and 3), and that the accumulation of osmoprotectants such as glycine-betaine is a common metabolic adaptation to salinity or drought stress in higher plants and other organisms (page 155 column 2 first full paragraph).

Rathinasabapathi et al. do not teach transgenic graminaceous plants or turfgrass, or a transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis*.

Hartman et al. teach a method of making transgenic turfgrass.

Xiao et al. teach an isolated nucleic acid encoding betaine aldehyde dehydrogenase from *Atriplex hortensis*.

Marcum teaches the accumulation of glycine betaine in turfgrass species in response to salt stress (page 783, Figure 6).

Given the teaching of Rathinasabapathi et al. that the accumulation of osmoprotectants such as glycine-betaine is a common metabolic adaptation to salinity or drought stress in higher plants and other organisms and their success of in making transgenic tobacco comprising transgenes encoding betaine aldehyde dehydrogenase obtained from plants, given the teaching of Marcum that turfgrass species accumulate glycine betaine in response to salt stress, and given that turfgrass transformation and an isolated nucleic acid encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* were known in the art at the time of Applicant's invention, it would have been *prima facie* obvious to one skilled in the art at the time the

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invention was made to transform a turfgrass plant with a transgene encoding betaine aldehyde dehydrogenase obtained from a plant such as *Atriplex hortensis*, given the express purpose of making a salt or drought tolerant transgenic turfgrass plant, without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 12, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

